UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,262	11/10/2000	Eugene Rosenberg	2290.00101	6244

7590 02/19/2003

Amy E Rinaldo
Kohn & Associates
30500 Northwestern Highway Suite 410
Farmington Hills, MI 48334

EXAMINER	
KERR, KATHLEEN M	
ART UNIT	PAPER NUMBER
1652	20

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/710,262	ROSENBERG ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. In response to the previous Office action, a Notice to Comply (Paper No. 17, mailed on October 24, 2002), Applicants filed a sequence listing received on November 5, 2002 (Paper No. 18). Said sequence listing brings the instant application into compliance with the sequence rules. Claims 1-16 are pending in the instant Office action.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

SuperGroup A. Claims 1-14, drawn to DNA sequences, vectors thereof, host cells thereof, cosmids there, classified in class 435, subclass 252.3.

SuperGroup B. Claims 1-14, drawn to amino acid sequences, classified in class 435, subclass 183.

SuperGroup C. Claim 15, drawn to methods of combinatorial genetics, classified in class 435, subclass 6.

SuperGroup D. Claim 16, drawn to methods of encoding for the synthesis, modification, or regulation of TA, classified in class 435, subclass 76.

Each SuperGroup is further restricted to the product or method of using the product as related to any one of SEQ ID NOs:1-19. Thus, the instant application is divided into 4*19=**76 total Groups**.

3. The inventions are distinct, each from the other because of the following reasons. For clarity, the Examiner will first cite distinctness within SuperGroups, then distinctness between members of one SuperGroup with respect to members of another SuperGroup.

The Groups within SuperGroup A (Groups 1-19) are related to each other as nucleic acids encoding polypeptides required for the synthesis of antibiotic TA. However, these nucleic acids encode enzymes which each have distinct functional properties catalyzing unique reactions in the biosynthetic pathway of the antibiotic TA. Furthermore, these nucleic acids encode enzymes having distinct structural properties with varying amino acid sequence, and thus varying nucleic acid sequence, lacking any consensus among the Groups. Thus, members of SuperGroup A (Groups 1-19) are patentably distinct, each from the other. While these Groups of DNAs are all identically classified, to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

The Groups within SuperGroup B (Groups 20-38) are related polypeptides required for the synthesis of TA antibiotic. These enzymes are distinct from each other for the reasons cited above for their encoding nucleic acids. Thus, members of SuperGroup B (Groups 20-38) are patentably distinct, each from the other. While these Groups of polypeptides are all identically classified (which classification may be amended as functions of the polypeptides are noted), to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

The methods of SuperGroup C (Groups 39-57) and SuperGroup D (Groups 58-76) are related, within their respective SuperGroups, as methods of using distinct nucleic acids encoding polypeptides involved in the synthesis of TA antibiotic. The methods within each SuperGroup are distinct from every other method in the SuperGroup for the reasons cited above for the distinctness of the nucleic acids and/or the enzymes. Thus, members of SuperGroup C (Groups 39-57) are patentably distinct, each from the other. Members of SuperGroup E (Groups 58-76) are patentably distinct, each from the other.

The DNA of SuperGroup A is related to the respective polypeptides of SuperGroup B by virtue of the fact that the DNA encode the polypeptides. The DNA molecule has utility for the recombinant production of the polypeptides in a host cell. Although the DNA and the polypeptides are related, they are distinct inventions because the polypeptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of polypeptides, such as nucleic acid hybridization assays. Therefore, members of SuperGroups A and B are patentably distinct, each from the other.

The DNA of SuperGroup A are related to the methods of SuperGroups C and D as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the DNA can be used for a materially different process of using the product, such as in the recombinant

production of the encoded proteins in an appropriate host cell. Thus, all members of SuperGroup A are patentably distinct from all members of SuperGroups C and D.

The polypeptides of SuperGroup B are related to the methods of SuperGroups C and D by virtue of the DNA that encodes the polypeptides being used in the methods. However, the polypeptides are neither used nor produced in the methods of SuperGroups C and D. Thus, all members of SuperGroup B are patentably distinct from all members of SuperGroups C and D.

The methods of SuperGroup C are distinct from the methods of SuperGroup D because the methods use wholly different process steps and reagents to produce wholly different products. Furthermore, these methods are not disclosed as being used together. Therefore, all members of SuperGroup C are patentably distinct from all members of SuperGroup D.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

5. The Examiner notes that if DNA product claims are found directed to an allowable product, then related process claims in SuperGroups C and D, which are directed to processes of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for

patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

6. A telephone call was made to Amy Rinaldo on February 10, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Suggested Claim Language

7. The Examiner suggests the following claim language in the instant application. If Applicants choose to amend the claims as suggested below, it is the responsibility of Applicants to identify specific (page and line number) support for the amended claim language in the specification as originally filed.

1. An isolated DNA sequence comprising a polynucleotide encoding a polypeptide selected from the group consisting of SEQ ID NOs: ___ (only encoded polypeptide seq ids should be here), wherein said polypeptide is required for the synthesis of antibiotic TA.

2. An isolated DNA sequence according to Claim 1, wherein said polynucleotide has a sequence as set forth in and one of SEQ ID NOs: ___ (only DNA seq ids that encode the polypeptide SEQ IDs in Claim 1 as taught by the specification should be here).

3. An isolated DNA sequence according to Claim 2, wherein said DNA is SEQ ID NO: ___ (only one DNA seq id that encodes the polypeptide SEQ ID in Claim 1 as taught by the specification should be here).

4. A vector comprising the DNA sequence according to Claims 1 or 2.

5. A vector, according to Claim 4, further comprising a promoter sequence operatively linked to said DNA.

6. A host cell transformed with the vector according to Claim 5.

7. An *E. coli* host cell transformed with the vector according to Claim 5.

8. A method of making a polypeptide comprising the following steps:
   a) culturing a host cell according to Claim 6 under such conditions that the encoded polypeptide is expressed, and
   b) isolating said encoded polypeptide.

9. An isolated polypeptide required for the synthesis of antibiotic TA, said polypeptide having a sequence as set forth in and one of SEQ ID NOs: ___ (only polypeptide seq ids should be here).

Conclusion

8. A complete response to the instant Office action **must** include an election of invention (SuperGroup ***PLUS*** a SEQ ID NO) to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
February 10, 2003